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Monday
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Part VI

Environmental Protection Agency

Health and Safety Data Reporting; Submission of Lists and Copies of Health and Safety Studies

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 716

[OTS-084003; FRL 1359-6]

Health and Safety Data Reporting; Submission of Lists and Copies of Health and Safety Studies

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; notice of opportunity for comment.

SUMMARY: This rule would require submission of health and safety studies on specifically listed chemicals by chemical manufacturers, processors, distributors, and others in possession of such studies. These chemicals have either been recommended by the Interagency Testing Committee for testing under section 4 of the Toxic Substances Control Act (TSCA) or separately selected by the Environmental Protection Agency for evaluation. The Administrator will use these studies to assess the health and environmental effects of the chemicals and the need for and character of testing rules to be promulgated under section 4(a) of TSCA. In order to obtain health and safety studies on additional chemicals in the future, the Administrator will amend this rule from time to time by adding to the list of chemicals subject to the rule.

DATES: Comments must be received on or before February 29, 1980.

ADDRESS: Written comments should bear the document control number OTS-084003 and should be submitted to the Document Control Officer, Office of Toxic Substances (TS-793), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460. All written comments filed pursuant to this notice will be available for public inspection at the OTS reading room at the above address from 9:00 a.m. to 5:00 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Mr. John B. Ritch, Industry Assistance Office (TS-799), Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460, 800-424-9065 toll free; in Washington, D.C., please call 554-1404.

SUPPLEMENTAL INFORMATION:

Authority and General Purpose

Section 8(d) of TSCA (15 U.S.C. 2607(d)) authorizes the Administrator to promulgate rules under which the Administrator shall require submission of lists and copies of health and safety studies on chemical substances or mixtures.

Persons who may be required to submit lists of studies are persons who manufacture, process, or distribute in commerce the substances or mixtures or who propose to do so. The studies to be listed are those conducted at any time by or for such persons, or known to such persons, or reasonably ascertainable by such persons.

These same persons may be required to submit copies of studies listed by or otherwise known by them. Moreover, any person who possesses a study that is on a submitted list or that is otherwise known to him may be required to submit that study. Section 8(f) of TSCA (15 U.S.C. 2607(f)) states that for purposes of section 8, the terms "manufacture" and "process" mean manufacture or process for commercial purposes. therefore, manufacturers and processors who are potentially subject to the requirement to submit lists under section 8(d) are those who manufacture or process chemical substances and mixtures for commercial purposes.

This notice proposes a rule under the authority of section 8(d). The proposed rule sets forth requirements and procedures for submission of lists of health and safety studies by manufacturers, processors, and distributors in commerce of chemical substances and mixtures, and for submission of copies of final reports by persons in possession of studies. The lists and copies of health and safety studies would be submitted on chemicals specifically listed in 40 CFR 716.13 of the proposed rule. The Agency intends to collect information on additional chemicals in the future by adding to the chemicals listed in this rule. The collected studies will be used by EPA in evaluating health and environmental effects of chemicals as well as in determining whether the chemicals should be included in testing rules issued under section 4 of TSCA.

The Interagency Testing Committee (ITC), established under section 4(e) of TSCA (15 U.S.C. 2603(e)), recommends chemical substances, categories of substances, and mixtures for priority consideration by EPA in the issuance of testing rules under section 4(a) of TSCA (15 U.S.C. 2603(a)). Section 4(e) directs the ITC to revise the list every six months as it is determined to be necessary. The Agency is developing this rule to obtain health and safety studies relating to each group of substances and mixtures selected by the ITC as well as other chemicals separately selected by EPA for evaluation of health and environmental effects. As EPA develops testing rules under section 4, it expects to propose additions to the list of chemicals subject to this section 8(d) rule. The purpose of the additions will be to assist EPA to obtain any existing information which could provide guidance as to the kinds of testing needed or which could make further testing unnecessary. This section 8(d) rule will also be applied to gather information which will be used by the Agency in its other regulatory functions.

Background

On July 18, 1978, EPA promulgated a rule similar to the one proposed in this notice (43 FR 30984). That rule required persons who manufacture, process, or distribute in commerce the chemicals on the first ITC priority list to submit lists and copies of health and safety studies on those chemicals. The rule was corrected in two minor respects shortly after its promulgation (43 FR 36249, 43 FR 41205).

On September 12, 1978, the Manufacturing Chemists Association (MCA) filed a petition requesting EPA to amend or repeal the July 18 rule. With minor exceptions, EPA rejected the petition. The issues raised by MCA and EPA's responses to those issues are set forth at 43 FR 56724.

On September 15, 1978, Dow Chemical Company (Dow) filed a petition for review of the rule in the United States Court of Appeals for the Third Circuit, *Dow Chemical Company* v. *United States Environmental Protection Agency, No. 78-2203.* Dow's petition challenged two provisions of that rule on the following grounds relating to the scope of the Agency's statutory authority. First, Dow asserted that EPA does not have the authority to obtain studies on chemicals manufactured or processed for research and development purposes since it was claimed such chemicals are not manufactured or processed for commercial purposes. Second, Dow asserted that EPA does not have the authority under section 8(d) to obtain copies of studies on a chemical from companies that do not manufacture, process or distribute that chemical. These issues were also raised by MCA in its petition.

In addition, Dow asserted that EPA did not provide adequate notice and fair opportunity to comment with respect to provisions in the July 18 rule that required persons subject to the rule to submit studies on acute effects of chemicals and that required companies to submit studies on chemicals they do not manufacture, process, or distribute.

Dow's challenge of EPA's interpretation of its statutory authority was denied on August 24, 1979. The court ruled that (i) chemicals

manufactured or processed for research and development are manufactured or processed for commercial purposes and (ii) that the EPA has the authority under 8(d)(2) to require persons to submit copies of studies on chemicals that they do not manufacture, process, or distribute. However, we are soliciting comments on whether we should exercise the full extent of our authority on these and other provisions of the proposed rule.

During the proceedings in the Dow lawsuit, the following became apparent. Reporting under the rule was substantially completed by October 16, 1978. Dow did not request a judicial stay of the rule but submitted a substantial number of studies and presumably complied with the rule. It appeared that EPA had received almost all the important information it would receive under the subject rule. In addition, EPA was in the process of developing another rule under section 8(d) for the purpose of obtaining health and safety studies on other chemicals recommended by the ITC, and Dow and others would have adequate opportunity to again raise all of the issues when that next section 8(d) rule was proposed. Also, EPA decided that Dow had raised substantial questions on whether adequate notice and comment were provided with respect to some provisions of the July 18 rule, although EPA entertained no doubt that the provisions of the rule were within the Agency's statutory authority. All of the above considerations led EPA to revoke the July 18 rule.

In the notice of revocation (44 FR 6099), EPA stated its opinion that it had the authority to obtain studies from persons who manufacture or process chemicals for research and development and to obtain copies of studies on substances from persons in possession of such studies whether or not they manufacture, process, or distribute the substances. However, EPA stated that it would accept comments on the issue of whether under any given section 8(d) rule it should exercise the full extent of its authority.

The notice also stated that since EPA had already received substantial information under the July 18 rule, it had determined that it would best use its resources by revoking that rule and considering all issues at a later date in a rule covering both the chemicals subject to the July 18 rule and additional chemicals recommended by the ITC and other chemicals separately selected by EPA. In this way, all of the controversy could be addressed in the context of a rule with future effect rather than a rule which had already been complied with and would soon be superseded in any event.

This present proposed rule requires reporting of lists and copies of studies on all chemicals included in the July 18 rule, as well as additional chemicals recommended by the ITC and other chemicals separately selected by EPA. While EPA is proposing a rule that would exercise authority substantially similar to that exercised in the July 18 rule, the agency specifically requests comment on whether it should exercise such authority as a matter of policy. Any comment the agency receives on this matter will receive serious consideration before any final decision is made.

Chemical Substances Subject to the Rule

40 CFR 716.13 of the proposed rule contains, and will be expanded in the future to contain, all chemical substances selected by the ITC (see 42 FR 55026, 43 FR 16684, 43 FR 50630, 44 FR 31866) as well as other chemicals separately selected by EPA. The list of chemicals and categories of chemicals in 40 CFR 716.13 includes chemicals other than those so far recommended for testing by the ITC. Of these, several are among substances for which the ITC has estimated exposures and potential for adverse effects as part of its selection process. EPA considered these exposure and effects rankings in choosing these chemicals for further investigation. Asbestos, chlorinated dioxins, and chemicals associated with production of chlorinated dioxins are also included. Asbestos and chlorinated dioxins are known to adversely affect health. To assess the scope of potential adverse effects on health and the environment of each listed chemical, the Agency is proposing to gather existing unpublished studies by means of this rule.

General Requirements of the Rule

This proposed rule would require manufacturers, processors, distributors, and others possessing studies to submit health and safety data relating to the chemical substances and mixtures listed in 40 CFR 716.13 of the rule. The rule proposes two types of submission requirements—the requirement to submit copies of final reports of health and safety studies (with an appropriate index-list) and the requirement to submit lists of certain additional health and safety studies.

The requirement to submit copies of studies would be applied in two ways. First, when the rule goes into effect, all manufacturers, processors, and distributors of chemical substances or mixtures would be required to submit copies of any final reports they possess of unpublished studies on any chemical substance or mixture listed in 40 CFR 716.13 of the rule. Second, EPA may request copies from persons other than manufacturers, processors, and distributors when such person is identified as possessing a study that is listed by someone else in accordance with 40 CFR 716.16 of the rule. Such persons would be required to submit studies only upon written request by the EPA.

This copy submission requirement applies to any manufacturer, processor, or distributor whether or not a company has ever manufactured, processed, or distributed the chemical that is the subject of the study or has ever proposed to do so.

Section 8(d)(2) of TSCA Permits EPA to require *any person* to submit a copy of *any* study in his possession. However, EPA believes that the two requirements described above will be effective, and, therefore it may not be necessary to require submission of copies of final reports of studies from everyone possessing them. Persons in research laboratories of universities and other institutions for instance are likely to publish their findings; hence, little would be gained in including them in the proposed requirement. Moreover, such persons who possess unpublished studies would be covered by the requirement to submit them in response to a letter if the studies are listed in accordance with 40 CFR 716.16.

Although EPA is presently proposing to require submission of copies from any chemical manufacturer, processor, or distributor, EPA is considering whether to further limit the copy submission requirement for those persons. One alternative under consideration would require the manufacturer, processor, or distributor of any one chemical listed in 40 CFR 716.13 to submit copies of studies it possesses on any listed chemical. Another alternative under consideration would require any person who manufactured, processed, or distributed a listed chemical(s) or proposed to do so since January 1, 1950, to submit copies of studies on that chemical(s). The January 1, 1950, date was chosen because the experimental methods after this date generally utilize more advanced analytical techniques, such as, gas and column chromatography, high pressure liquid chromatography, and radio tracer techniques.

EPA desires specific comments on these alternatives and on any others it might use to obtain copies of health and safety studies.

The requirement to list studies would be applied to *current* manufacturers,

processors, and distributors of chemicals which are the subject of the studies and those who propose to manufacture, process, or distribute the chemicals. The persons subject to this requirement are only responsible for listing studies on the chemicals which they manufacture, process, or distribute. These persons must submit lists of ongoing studies conducted by or for them and studies known to them but not in their possession. This means for example that a company would have to include on its list studies referenced in memoranda in its files, thereby necessitating a more extensive file search than that required by a company submitting studies in its possession. EPA believes this is consistent with the intent of Congress to place a greater burden to submit information concerning a particular chemical on the manufacturer, processor, or distributor of that chemical. Such persons should naturally bear greater responsibility for submitting information related to any threat to the public that may occur from their particular chemical.

Specific Definitions

Section 8(d) applies in part to persons who manufacture, process, or distribute in commerce chemical substances and mixtures and to persons who propose to do so. TSCA sections 3(7) and 3(10) define "manufacture" and "process". Section 8(f) states that, for purposes of section 8, "manufacture" and "process" mean manufacture and process "for commercial purposes". The terms "manufacture for commercial purposes" and "process for commercial purposes" are specifically defined in the proposed rule.

The term "manufacture" is defined in section 3(7) of TSCA to include manufacture, importation, and production. The term "process" is defined in section 3(10) of TSCA to mean preparation of a chemical substance or mixture for distribution in commerce in the same or different form or physical state from that in which it was received, or as part of an article containing the chemical substance or mixture. Thus, a paint formulator placing a solvent in the product intended for distribution in commerce is a processor (of the solvent) as defined in TSCA.

EPA interprets the term "manufacture or process for commercial purposes" to refer to such activities conducted, in whole or in part, for the purpose of obtaining a commercial advantage for the manufacturer or processor. This may be distinguished from strictly charitable or purely academic activities. TSCA places the responsibility for gathering information in support of chemical regulation on those persons who will derive the commercial benefits from those chemicals.

Chemicals manufactured for product research and development would fall within the scope of this rule because these chemicals are produced for the potential commercial benefit of the manufacturer.

Health and safety studies of chemicals at the research and development stage may be of substantial benefit to EPA in evaluating chemical hazards. In the case of chemicals that have yet to be marketed, such studies enable EPA to evaluate the potential hazards of chemicals and take action to prevent harm before a chemical becomes firmly entrenched in the marketplace and becomes difficult to remove becaue of the economic and social dislocations that would occur. Also, a company may perform research and development on a chemical that it does not market, but is marketed by another company. Such a chemical may be marketed in substantial quantities and there may be considerable human and environmental exposure. In addition, tests performed at the research and development stage may provide the best available information on the effects of related chemicals. Again, such related chemicals may already be in the marketplace but no significant health and safety studies may ever have been conducted on them. Even at the research and development stage, chemicals may be produced in large quantities that could result in significant exposure. Furthermore, a company performing research and development may perform a study that shows a new chemical is too toxic to market and decide not to market it. If EPA cannot find out about the study, the Agency may permit marketing of the chemical in substantial quantities by another company. EPA also has an interest in obtaining information necessary to protect laboratory workers who are involved in research and develoment.

Chemicals that occur as byproducts or impurities from the manufacturing or processing of other chemicals are also considered to be manufactured or processed "for commercial purposes" even though they may have no commerical purpose separate from the substance, mixture, or article to which they are incidential. See Inventory Reporting Regulations 40 CFR 710, 4(d); 42 FR 64577 (1977). The legislative history of TSCA indicates that a broad interpretation of the term "commercial purpose" was intended. Specifically addressing the definition of "for commercial purposes," the House Committee stated:

> By use of the term "for commercial purposes," the Committee does not intend to restrict coverage to substances manufactured or processed "for sale." Any commercial purpose such as use as a chemical intermediate in a manufacturing process, is sufficient to bring the manufacture or processing of a substance within the ambit of [the Act]. H.R. Rep. No. 94–1341, 94th Cong., 2d Sess. 30 (1976)

Chemical intermediates which never leave the manufacturing plant and which are not manufactured "for sale" or even "for distribution in commerce" nevertheless are manufactured for commercial purposes. Likewise, byproducts or impurities not manufactured "for sale" are considered by EPA to be manufactured for commercial purposes.

When a company manufactures a particular chemical substance or mixture for commercial purposes, other chemicals may be produced concurrently. These other chemicals may be byproducts that are separated from the principal commercial products and sold, used, or discarded, or they may remain in the manufactured chemical as impurities. These byproduct chemicals that are developed for sale or use as commercial products, of course, are manufactured for commercial purposes. EPA interprets TSCA to mean that the discarded byproducts and the impurities, although they may have no commercial purpose separate from the chemical product with which they are associated, are also manufactured or processed for "commercial purposes." The Agency notes further that a byproduct discarded by one manufacturer may be developed for sale by another. In either case the byproduct is manufactured for commercial purposes.

EPA does not believe that one manufacturer should be able to avoid listing a study on the byproduct simply because the byproduct is discarded, since EPA believes that many substances which occur as byproducts or impurities may be more hazardous than the chemical substance or mixture with which they are associated. If the Agency is to carry out the purpose of the Act, it must obtain studies on these materials. An example of this situation is the case of chlorinated dioxins, highly toxic chemicals which appear as impurities or byproducts from the manufacture of certain halogenated phenols, such as, 2,4,5-trichlorophenol and pentachlorophenol. The chlorinated dioxins that occur as impurities are typically carried along in the processing of the products in which they are found.

Chlorinated dioxins, accordingly, are covered by this rule as chemicals manufactured or processed "for commercial purposes."

"Propose to manufacture, process, or distribute" is defined in this rule to mean that a person has made a management decision to commit financial resources toward the manufacture, processing, or distribution of a chemical substance or mixture. Thus, a person who purchases small amounts of a chemical substance for research and development would have to report any health and safety studies when management proposes to process or manufacture the substance for commercial purposes.

"Health and safety study" is defined in this rule as it is defined in section 3(6) of TSCA. However, examples have been added to the definition of "health and safety study" for illustrative purposes. Examples are of types of studies which are included in the definition of health and safety study. Studies of the following effects are included: carcinogenicity, mutagenicity, pharmacological effects, cumulative or synergistic effects, and any other effect regardless of severity. Environmental studies include chemical fate, persistence, and chemical-physical constants, as well as ecological effects. Other kinds of studies, such as monitoring studies, both workplace and environmental, are included. Although this is not an exclusive list, it illustrates the types of studies that should be submitted.

This proposed rule applies to health and safety studies of any effect for the listed substances. The Agency proposes to acquire and evaluate studies of any health and environmental effects associated with chemicals both for the development of section 4 testing rules and to fulfill other purposes of TSCA. It is important to know the full range of possible toxic effects of a substance in evaluating and predicting its biological activities. Chemical fate and persistence studies will help in predicting environmental contamination. Studies of acute effects will help in assessing the potential of chemicals to cause adverse effects in the environment, as well as indicating the possibility of other health effects. Acute effects studies designed to measure potential ecological effects are especially valuable since there is comparatively less information in this field than in others. Also, the submission of acute effects studies will be used to determine the need for and character of acute-effects testing rules.

"Copies of Health and Safety Studies" as defined in this rule means copies of final reports from the principal investigators of health and safety studies. This is intended to circumvent endless review of studies by persons other than the principal investigators of the studies. A health and safety study is final when a report is available from the principal investigator, not when it is available after management review. Management, of course, has an independent responsibility and right to review a study after it is submitted to EPA.

The term "known to" when applied to a health and safety study means to have direct or indirect knowledge of the existence of the study. For example, a company may directly know that a study exists because the company has the study in its possession or because another person has given the company a written report about it. A company has possession of a study when the study is contained in the official files of that company or in the files of any employee. Similarly, a company may indirectly know that underlying data are in the possession of a testing laboratory because the laboratory performed the study for the company or may indirectly know of a study because it is referenced in a memorandum in the files of an employee.

Reporting Schedule

Persons would be required to submit lists and copies of studies on or before 60 days from the effective date of promulgation of the list of chemical substances and mixtures in 40 CFR 716.13. This proposed rule does, however, include a provision for extending the submission deadline by 20 days. Extensions will only be granted because of extraordinarily long file searches.

Persons would have a continuing duty to submit lists of any studies initiated within five years after the date the chemical substance or mixture was added to the list in 40 CFR 716.13. Copies of final reports of studies listed as ongoing, or studies initiated within the five year reporting period, would have to be submitted within 30 days of the date they are obtained by persons required to report.

Sunset Provision

Requirements to report information under this rule would expire on a date within five years after the chemical to which the information pertains is added to the list in 40 CFR 716.13. If EPA determines that reporting should be continued, a notice to that effect will be published for comment.

Proposed Method for Adding ITC Chemicals to the Rule

The Agency is proposing adding the following provision to 40 CFR 716.13 of the proposed rule: "Upon publication in the FEDERAL REGISTER of the list of chemicals recommended for testing by the ITC, those chemicals become immediately subject to the provisions of this rule." The Agency is soliciting comments on this proposed provision.

Confidentiality

The Agency has interpreted section 8(d) to permit broad access to information. However, EPA is very much aware of the need to maintain the confidentiality of any legitimate trade secrets. Accordingly, every effort will be made under EPA's procedures to preserve confidential commercial information.

A person submitting a health and safety study under 40 CFR 716.15, 716.16, or 716.17 *may claim all or part of the study confidential.* However, the Agency is authorized by section 14(b) of TSCA to withhold health and safety data from disclosure only to the extent that disclosure would reveal (1) processing information and (2) percent composition of mixtures. Other information contained in the study, the disclosure of which would clearly be an unwarranted invasion of personal privacy (such as individual medical records), will be considered confidential as provided in title 5, United States Code, section 552(b)(6). The provisions of section 14(b) apply only to health and safety data concerning chemical substances or mixtures that (1) have been offered for commercial distribution or which are in the inventory of chemical substances under section 8(b) of TSCA or (2) for which testing is required under section 4 of TSCA or for which notification is required under section 5 of TSCA (See 44 FR 17673).

Any claims of confidentiality must be made at the time of submission, as provided in 40 CFR 2.203(a)(2) and in the manner specified in 40 CFR 716.21 of this proposed regulation. This rule contains a provision to require submission of two copies of studies containing confidential material—one copy indicating what data are claimed as confidential and one copy without the confidential information. EPA will presumptively consider failure to submit two copies as a waiver of the confidentiality claim. However, EPA will notify respondents who claim parts of studies confidential that they did not submit the required two copies. This provision affords persons the opportunity to correct errors and thus

prevent data claimed as confidential from being placed in the public file. To ensure proper handling of confidential material, submissions must be addressed to the Document Control Officer of the Office of Toxic Substances.

Economic Impact

EPA estimates that the total cost to industry of submitting lists and copies of health and safety studies on the listed chemicals at approximately $411,000.

The major cost of compliance with the section 8(d) requirements will be the cost of a file search to determine what health and safety studies are in the possession of the firm. It is assumed that during the file search for studies, the files will also be searched for references to studies that are not in the firm's possession. This cost will, of course, vary directly with the size of the firm, due to the assumption that larger firms have more files at more locations which must be accessed. Once the studies are located, the remaining compliance costs involve copying and processing the studies, making lists of studies which are in progress or not in the possession of the respondent, and reviewing the studies for confidential information. Each of these costs is outlined below.

File search	$111,120
Title and protocol listing	13,890
Photocopying (materials)	11,748
Photocopying (labor)	39,160
Managerial review	234,960
Total cost to industry	410,878

If we assume a ±30% margin or error in these estimates, the range of probable cost could vary from $288,000 to $534,000.

Spread over the entire chemical industry, such a cost is extremely minor. Furthermore, if the studies submitted allow EPA to forego even one secton 4 testing rule on a subject chemical, the cost avoided thereby would exceed the total cost of the section 8(d) rule.

Public Meetings

During the 60-day comment period, EPA personnel responsible for developing this proposal will be available to meet with interested persons from companies, trade associations, organized labor, and citizen organizations to discuss the proposal. EPA will provide facilities and make other necessary arrangements for such meetings. The Agency will make transcripts or summaries of the meetings for inclusion in the official public record.

Persons should call EPA's Industry Assistance Office at the number listed under "For Further Information Contact" above to request time for such a meeting or more information on them.

Most meetings will be held at EPA in Washington, D.C. However, in line with EPA's desire to facilitate input from smaller companies and local organizations, the Agency would hold a meeting outside of Washington in a locale central to a group requesting such a meeting where there is demonstrated interest in and need for it.

While the meetings will be open to the public, participation will be limited to those requesting the session and EPA personnel designated for the session.

Public Record

EPA has established a public record (docket number OTS-084003) for this proposed rulemaking document, which along with a complete index is available for inspection in the OTS Reading from 9:00 a.m. to 5:00 p.m. on working days (401 M Street, SW, Washington, DC, 20460). This record includes basic information considered by the Agency in developing this Proposed Rule. The Agency will supplement the record with additional information as it is received. The record includes the following categories of information:

(1) Health and Safety Study Reporting Regulations, July 18, 1978, Public Record, Docket No. 084001.

(2) Manufacturing Chemists Association—Petition under section 21 of TSCA, September 12, 1978.

(3) Denial of Citizens' Petition, 43 FR 56724-56727.

(4) The entire docket in *Dow Chemical Company v. United States Environmental Protection Agency, et. al. Docket No. 78-2203 (3rd Cir.).*

(5) Revocation of Rule, 44 FR 6099.

(6) Reports Impact Analysis of This Proposed Rulemaking Document.

EPA anticipates adding to the rulemaking record the following types of information:

(1) All comments on this proposed rule.

(2) All relevant support documents and studies.

(3) Records of all communications between EPA personnel and persons outside the Agency pertaining to the development of this rule. (This does not include any inter- or intra-agency memoranda unless specifically noted in the index of the rulemaking record).

(4) Minutes, summaries, or transcripts of any public meetings held to develop this rule.

(5) Any factual information considered by the Agency in developing the rule.

EPA will identify the complete rulemaking record on or before the date of promulgation of the regulation, as prescribed by section 19(a)(3) of TSCA, and will accept additional material for inclusion in the record at any time between this notice and such designation. The final rule will also permit persons to point out any errors or omissions in the record.

Note.—EPA has determined that this document does not contain a major proposal requiring preparation of a Regulatory Analysis under Executive Order No. 12044.

Dated: December 18, 1979.

Douglas M. Costle,

Administrator.

It is proposed that Title 40, Chapter I, be amended by adding the new Part 716 to read as follows:

PART 716—HEALTH AND SAFETY DATA REPORTING

Sec.

716.11 Scope and compliance.
716.12 Definitions.
716.13 Substances to which this Part applies.
716.14 [Reserved]
716.15 Requirement to submit copies of studies.
716.16 Requirement to submit lists of studies.
716.17 Persons in possession of listed studies.
716.18 Information not subject to mandatory reporting.
716.19 Schedule for submission of studies.
716.20 Sunset provision.
716.21 Confidentiality claims.

Authority: Secs. 8(d) and 14(c), Pub. L. 94-469, 90 Stat. 2029 (15 U.S.C. 2607(d)) and 90 Stat. 2035 (15 U.S.C. 2613(c)).

§ 716.11 Scope and compliance.

(a) This Part sets forth rules to require submission of lists and copies of health and safety studies on chemical substances and mixtures selected for priority consideration for testing rules under section 4(a) of the Toxic Substances Control Act (TSCA) and on other chemical substances and mixtures for which EPA requires health and safety information in fulfilling the purposes of TSCA.

(b) Section 15(3) of the GSCA makes it unlawful for any person to fail or refuse to timely submit information required under this Part. Section 16 provides that a violation of section 15 renders a person liable to the United States for a civil penalty and possible criminal prosecution. Under section 17, the district courts of the United States have jurisdiction to restrain any violation of section 15.

§ 716.12 Definitions.

The definitions set forth in section 3 of TSCA apply to this Part. In addition, the following definitions are provided for the purposes of this Part:

(a) "EPA" means the United States Environmental Protection Agency.

(b) "Copies of Health and Safety Studies" means copies of final reports from the principal investigator(s).

(c) "Health and safety study" means any study of an effect of a chemical substance or mixture on health on the environment or on both, including underlying data and epidemiological studies, studies of occupational or environmental exposure to a chemical substance or mixture, toxicological, clinical, and ecological or other environmental studies of a chemical substance or mixture, and any test performed under TSCA.

(1) Examples are:

(i) Long- and short-term tests of mutagenicity; carcinogenicity; or teratogenicity; data on behavioral disorders; dermatoxity; pharmacological effects; mammalian absorption; distribution; metabolism and excretion; cumulative, additive, and synergistic effects; and acute, subchronic, and chronic effects.

(ii) Tests for ecological or other environmental effects on invertebrates, fish, or other animals, and plants, including: acute toxicity tests, chronic toxicity tests, critical life safe tests, behavioral tests, algal growth tests, seed germination tests, plant growth or damage tests, microbial function tests, bioconcentration or bioaccumulation tests, and model ecosystem (microcosm) studies.

(iii) Assessments of the human and environmental impacts of a particular chemical substance, including surveys, tests and studies of: biological, photochemical, and chemical degradation; air, water and soil transport; biomagnification and bioconcentration; and chemical and physical constants (e.g., boiling point, vapor pressure, evaporation rates from soil and water, octanol-water partition coefficient, and water solubility).

(iv) Studies measuring or estimating concentrations of a particular chemical(s) anywhere in the environment, including the workplace.

(v) Studies measuring or estimating human or environmental exposure to a particular chemical(s) anywhere in the environment, including the workplace.

(vi) Industrial hygiene surveys; and

(vii) For purposes of this Part, individual files and medical records, lab notebooks, data points, daily monitoring records, etc. are considered to be underlying data.

(2) A health and safety study on a mixture containing a particular chemical substance is a health and safety study on the chemical substance to the extent the study reflects the effect(s) of the substance.

(d) "Importer" means any person who imports a chemical substance, including a chemical substance as a part of a mixture or article, into the Customs Territory of the United States and includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his behalf (as defined in 19 CFR 1.11). Importer also includes, as appropriate:

(1) The consignee.

(2) The importer of record.

(3) The actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20.

(4) The transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with Subpart C of 19 CFR 144.

For the purpose of this definition, the Customs Territory of the United States consists of the 50 States, Puerto Rico, and the District of Columbia.

(e) "Known to" means that a person has direct or indirect knowledge of the existence of certain information. Direct knowledge means that a person has a study in his possession or knows of the study because he has been given a written report. Indirect knowledge means that a person knows of a study on the basis of written evidence in his files. This may occur when a testing laboratory has in its possession the underlying data for a study performed for the person subject to this rule or when a study is referenced in a memorandum in the files of the person or any employee of the person.

(f) "Manufacture" and "Process" means manufacture or process for commercial purposes.

(g)(1) "Manufacture for commercial purposes" means to import, produce, or manufacture with the purpose of obtaining an immediate or eventual commercial advantage for the manufacturer, and includes, among other things, such "manufacture" of any amount of a chemical substance or mixture,

(i) For commercial distribution, including for test marketing, and

(ii) For use by the manufacturer, including use for product research and development, or as an intermediate.

(2) "Manufacture for commercial purposes" also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value. They are nonetheless produced for the purpose of obtaining a commercial advantage since they are part of the manufacture of a chemical product for a commercial purpose.

(h) "Person" includes any individual, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity, any State or political subdivision thereof, any municipality, any interstate body, and any department, agency, or instrumentality of the Federal Government.

(i) "Possession" means that a person who is not a natural person has "possession" of a study when the study is contained in the official files of that person or in the files of any employee of that person.

(j) "Process for commercial purposes" means the preparation of a chemical substance or mixture, after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included. If a chemical substance or mixture containing impurities is processed for commercial purposes, then those impurities are also processed for commercial purposes.

(k) "Propose to manufacture, process, or distribute" means that a person has made a management decision to commit financial resources toward the manufacture, processing, or distribution of a chemical substance or mixture.

(l) "Protocol" means a detailed description of the study and conduct to be followed.

(m) "TSCA" means the Toxic Substances Control Act, 15 U.S.C. 2601 *et. seq.*

§ 716.13 Substances to which this Part applies.

The requirements of this Part apply to the chemical substances and mixtures listed below.

(a) As of (the date the final regulations are published in the Federal Register) the requirements of this Part apply to the following:

	CAS Numbers (examples for groups)
Acetonitrile	75-05-8.
Acrylamide	79-06-1.
Acrylic acid and 2-methylacrylic acid and their esters.	79-10-7 etc.
Acrylonitrile	107-13-1.
Alkyl epoxides—including all noncyclic aliphatic hydrocarbons with one or more epoxy functional groups.	75-21-8, 75-56-9, 106-88-7, 564-00-1, etc.
Alkyl phthalates—all alkyl esters of 1,2-benzene dicarboxylic acid (orthophthalic acid).	117-81-7, 26761-40-0, etc.

	CAS Numbers (examples for groups)
Aniline and chloro-, bromi-, and/or nitro-anilines.	142-04-1, 95-51-2, 108-42-9, 106-47-8, 95-76-1, 634-93-5, 106-40-1, 88-74-4, 99-09-2, 100-01-6, 97-02-9, 121-87-9, 89-63-4, 99-30-9, 3531-19-9, 827-94-1, 1817-73-8, 99-29-6.
Antimony	7440-36-0.
Antimony trioxide	1309-64-4.
Antimony sulfide	1345-04-6.
Aryl phosphates—phosphate esters of phenol or of alkyl-substituted phenols. Tri-aryl and mixed alkyl and aryl esters are included, but trialkyl esters are excluded.	26444-49-5, 115-86-6, 1330-78-5, etc.
Asbestos—naturally occurring mineral silicates; chrysotile, amosite, crocidolite, tremolite, actinolite, and anthophyllite.	1332-21-4, 12001-29-5, 12172-73-5, 17068-78-9.
Benzene	71-43-2.
Benzene (epoxyethyl)	96-09-3.
Bisazobiphenyl dyes and pigments derived from benzidine and its congeners, orthotolidine (dimethylbenzidine), dianisidine (dimethoxybenzidine), and dichlorobenzidine.	
DYES DERIVED FROM BENZIDINE	
Direct Black 4	2429-83-6.
Amidine Black RBN	
Direct Black RX	
Direct Black RW Ex. Conc.	
Direct Black 38	1937-37-7.
Amidine Black GA 200%	
Diazol Black JXA Double	
Direct Black E 200%	
Direct Black E Ex. Conc. New	
Direct Black BHX	
Direct Black GAC Conc. 200%	
Direct Black GX 200%	
Elcomine Direct Black CP Conc.	
Elcomine Direct Black GXP 200%	
Orcomine Direct Black GX 200%	
Synodirect Black GAC	
Direct Blue 2	2429-73-4.
Amidine Diazo Black BHSW Conc.	
Diazo Black BH	
Diazol Black BHA	
Elcomine Black BH	
Elcomine Navy Blue Btt	
Orco Diazo Black BH 125%	
Direct Blue 6	2602-46-2.
Amidine Blue 2B Conc.	
Direct Blue 2B 250%	
Direct Blue 2B Conc.	
Direct Fast Blue 2B Conc.	
Elcomine Blue 2B 250%	
Synodirect Blue 2B 100%	
Direct Brown 1A	3611-71-0.
Amidine Brown 3GC 250%	
Elcomine Brown D3G Conc.	
Direct Brown 2	2429-82-5.
Amidine Brown M Conc. New	
Direct Brown M	
Elcomine Brown M Conc.	
Direct Brown 6	2893-80-3.
Direct Brown 2R	
Direct Brown 31	2429-81-4.
Direct Brown B 125%	
Direct Brown BCW	
Elcofast Brown B Conc.	
Solamidine B	
Direct Brown 59	3476-90-2.
Amidine Brown DMB	
Direct Brown 74	8014-91-3.
Direct Catechine 3G	
Elcofast Catechine 3G	
Direct Brown 95	6071-86-6.
Chrome Leather Brown	
Diazol Light Brown 6RN Ultra Conc.	
Direct Brown BRL	
Elcomine Brown BRLL	
Intralite Brown BRLL Conc.	
Synodirect Brown BRL 100%	
Direct Brown 154	6360-54-9.
Direct Brown 3GN	
Direct Brown CMD.	
Elcomine Brown 3GNP	
Direct Green 1	3626-28-6.
Amidine Dark Green N	
Chrome Leather Dark Green S Conc.	
Direct Green WS	
Elcomine Green WT	
Orcomine Dark Green WS	
Direct Green 6	4335-09-5.
Amidine Green 2BN	
Amidine Green M Special	
Direct Brilliant Green CBM Ex. Conc.	
Direct Green BX	
Direct Green MT 150%	
Elcomine Green MT 150%	
Orcomine Green BX	
Direct Green 8	5422-17-3.
Amidine Green GX	
Direct Orange 1	6507-81-9.
Orcolitefast Orange GLZ	
Direct Orange 8	2429-79-0.
Direct Fast Orange R	
Direct Paper Orange R Conc.	
Direct Orange R	
Elcomine Orange RP Conc.	
Paper Orange R	
Synodirect Orange Y 100%	
Direct Red 1	2429-84-7.
Amidine Fast Red F New	
Congo Red F	
Direct Fast Red F	
Elcofast Red FD	
Orcomine Red F	
Direct Red 28	573-58-0.
Congo Red	
Direct Congo Red 4B	
Elcomine Congo Red	
Orcomine Congo Red	
Synodirect Red 4B 100%	
Direct Red 37	3530-19-6.
Amidine Fast Scarlet BN Conc.	
Direct Fast Scarlet B	
Elcomine Scarlet B	
Orcomine Scarlet B	
Direct Violet 1	2586-60-9.
Amindine Violet N	
Elcomine Violet 3R Conc.	
Direct Violet 22	6426-67-1.
Elcomine Violet BW 200	
Acid Red 85	3567-65-5.
Intrazone Fast Red GRG	
Milling Red 2J	
Milling Scarlet G	
Nylon Fast Scarlet PG	
Supernylite Scarlet G	
DYES DERIVED FROM O-DIANISIDINE	
Direct Black 91	6739-62-4.
Cuprofix Black C-RL	
Cuprophenyl Black RL 200%	
Intramet Black GM	
Direct Black 114:	
Cupophenyl Black BWL	
Direct Black 118:	
Lumicrease Grey 3LBN	
Direct Blue 1	2610-05-1.
Amanil Sky Blue 6B	
Amanil Sky Blue FF	
Atlantic Sky Blue 6B Conc.	
Atlantic Sky Blue FF Ex. Conc.	
Calcomine Sky Blue 6 BX Conc.	
Diazol Blue 6BA Conc.	
Diphenyl Brilliant Blue FF Supra	
Direct Brilliant Sky Blue 6B Ex. Conc.	
Direct Sky Blue 6B	
Direct Sky Blue 6B Conc.	
Direct Sky Blue 6B Ex. 200%	
Direct Sky Blue 6B Ex. Conc. 300%	
Direct Sky Blue 6BHF	
Direct Sky Blue FF Ex. 200%, 300%	
Elcomine Sky Blue 6B 200%	
Pergasol Blue GA Conc.	
Phenamine Brilliant Blue 6B Conc.	
Pyrazol Sky Blue FF	
Direct Blue 8	2429-71-2.
Atlantic Azurine G Conc.	
Direct Azurine G	
Direct Azurine G Conc.	
Direct Blue 15	2429-74-5.
Amanil Sky Blue M Liquid	
Amidine Sky Blue 5B Ex.	
Atlantic Sky Blue A, Ex. Conc.	
Blue M Liquid	
Cartasol Blue 2GF	
Direct Sky Blue A Supra Conc. 125%	
Intrabond Liquid Sky Blue M	
Paper Sky Blue S Liquid 35	
Potamine Sky Blue M Liquid	
Direct Blue 22	2586-57-4.
Atlantic Direct Blue RW 100%	
Direct Blue RW Conc. 200%	
Direct Blue 76	16143-76-6.
Amafast Blue RW 16BLL	
Atlantic Resin Fast Blue 16BLL Conc.	
Atlantic Resin Fast Blue LLGG	
Diazol Light Blue 7JL U.C.	
Fastusol Brilliant Blue L2GU	
Resin Fast Blue 16BLL	
Superlitefast Brilliant Blue 16BLL	
Direct Blue 77	6441-88-9.
Pyrazol Fast Blue 2GLN	
Direct Blue 80:	
Atlantic Resin Fast Blue RLX	
Atlantic Resin Fast Blue 2RLL	
Elcofast Blue 2RL	
Fastusol Blue LRRU	
Intralite Blue 2RLL	
Pergasol Blue 4RAL	
Pyrazol Fast Blue RUL	
Resin Fast Blue 7RLL	
Sirius Supra Blue 2RL	
Solophenyl Blue ZRL	
Superlitefast Blue RL	
Superlitefast Blue RLE	
Intralite Blue NBLL	
Solophenyl Blue RBL	
Direct Blue 90:	
Pyrazol Fast Blue FGL	
Direct Blue 98	6656-03-7.
Atlantic Resin Fast Blue LLU	
Atlantic Resin Fast Blue LLU 200%	
Atlantic Resin Fast Blue LLUG	
Diazol Blue 3JLNA	
Direct Fast Navy BRN	
Fastusol blue LR	
Intralite Brilliant Blue L	
Pyrazol Fast Blue LUL	
Resin Fast Navy WRA	
Sirius Supra Blue BRL	
Direct Blue 100:	
Resin Fast Blue 3GLL	
Superlitefast GL	
Direct Blue 151	6449-35-0.
Diazo Fast Blue MP, MP Conc.	
Direct Blue R 100%, R. Conc.	
Elcofast Diazo Blue B Conc.	
Direct Blue 156:	
Cuprophenyl Navy Blue BL	
Intramet Navy Blue RL	
Direct Blue 160:	
Cupodiasol Light Navy RL	
Cuprofix Navy C-GRL	
Cuprophenyl Navy Blue RL	
Intramet Navy Blue R11 Conc. 200%	
Direct Blue 191:	
Resin Fast Blue 8GLN	
Superlitefast Blue 8GLN	
Direct Blue 218	10401-50-0.
Amafast Blue 3GAV Conc.	
Amafast Bond Blue 10GLP Conc., 10 GLPLiq.	
Bond Blue B	
Carta Blue VP	
Elcofast Bond Blue	
Fastusol Blue 9GLP Liq.	
Paper Blue 3 GAP	
Pergosol Blue 8GLP Liq.	
Pontimine Bond Blue B Liq.	
Pontimine Fast Blue 7GLN	
Pyrazol Fast Sky Blue 7GUL	
Resin Fast Blue 3GAV	
Sirius Supra Blue 5G	
Solophenyl Blue 8GL, 8GLP Liq.	
Superlitefast Blue WB	
Superlitefast Blue 8GUL	
Superlitefast Blue 3GLST	
Direct Blue 218/224:	
Intrabond Liquid Blue 8GLL	
Intralite Blue 8GLL	
Direct Blue 224:	
Atlantic Resin Fast Blue 7GUL	
Direct Blue 269 (o-anisidine):	
Potamine Blue AB Liq.	
Direct Brown 200:	

	CAS Numbers (examples for groups)
Limicrease Dark Brown 3LB	
Direct Yellow 68:	
Cuprophenyl Yellow RL Extra	
Intramet Yellow RL	
Direct Violet 93:	
Cuprophenyl Violet 3RL	
Azoic Blue Composition 2:	
Atlantic Printing Blue D-BC	
Atlantic Printing Blue D Pdr.	
Neutrazoic Blue AS Pdr.	
Neutrazoic Blue D	
Azoic Blue Composition 3:	
Atlantic Printing Blue GB	
Neutrazoic Blue GS Pdr.	
Neutrazoic Blue GN Pdr.	
Azoic Black Composition 4:	
Atlantic Printing Black 3G Pdr	
Direct Azoic Diazo Component 48	20282-70-6.
Atlantic Stable Blue B Pdr.	
Azonene Fast Blue B Salt	
Fast Blue D-ND Salt	
Fast Blue B Salt	
Fast Blue B-ND Salt	
Stable Blue B Base	
Axoic Coupling Component 3	91-92-9.
Naphthol AS-BR	
Naphthol AS-BR 20% Soln.	
Naphthol AS-BR, AS-BR Soln.	
Other Dyes Derived From O-Dianisidine:	
Atlantic Printing Black 2b Pdr.	
Atlantic Printing Black FOR Pdr.	
Neutrazoic Black 2B Pdr.	
Neutrazoic Black FOR Pdr.	
Neutrazoic Black GF 167% Pdr.	
Neutrazoic Black JN Pdr.	
Padazoic Black GLL Pdr.	
Padazoic Black RLL Pdr.	
Padazoic Black 2G 150% Pdr.	
Atlantic Resin Fast Blue ARL BFL	
Atlantic Resin Fast Blue BLA	
Atlantic Resin Fast Blue BLC	
Atlantic Resin Fast Blue BRN	
Atlantic Resin Fast Blue 8BGL	
Atlantic Resin Fast Blue 3GLL	
Atlantic Resin Fast Blue 5GLL	
Atlantic Resin Fast Blue 8GLN	
Atlantic Resin Fast Blue LB GL	
Atlantic Resin Fast Blue 6GKS	
Atlantic Resin Fast Blue 8GUM	
Atlantic Resin Fast Blue 9GLR	
Atlantic Resin Fast Blue UGLL	
Atlantic Resin Fast Blue FFBL	
Padazoic Blue GP Pdr.	
Padazoic Denim Indigo Blue G Pdr.	
Padazoic Navy Blue WS EX Pdr.	
Pontamine Blue WE Liq.	
Padazoic Brilliant Indigo 3B Pdr.	
Padazoic Denim Indigo Pdr.	
Atlantic Printing Brown GGN Pdr.	
Atlantic Printing Brown BR Pdr.	
Neutrazoic Brown Br Pdr.	
Padazoic Farmer Brown Pdr.	
Atlantic Resin Fast Grey LVL	
Superlitefast Grey LVL	
Superlitefast Rubine WLKS	
DYES DERIVED FROM O-TOLIDINE	
Acid Red 114	6459-94-5.
Amacid Milling Red PRS	
Atanyl Red RS	
Erionyl Red RS, RS 125%	
Intrazone Red BR	
Levanol Fast Red GG New	
Milling Red SWB	
Milling Red SWB Conc.	
Nylon Fast Red RM	
Nylonsan Red F-RS	
Orcoacid Milling Red RS	
Polar Red RS Conc. 125%	
Telon Fast Red GG New	
Acid Red 167:	
Nylosan Red F-BR	
Milling Red B	
Polar Red B	
Acid Black 209:	
Sella Fast Black FC	
Azoic Coupling Component 5	91-96-3.
Naphthol ASG, ASG 20% Soln.	
Naphthol AS-G	
Naphthol AS-G Soln.	
Azoic Yellow Composition 1:	
Atlantic Printing Yellow GN Dbl. Soln.	
Atlantic Printing Yellow GS Dbl. Soln., GS Pdr.	
Azogen Yellow GS	
Neutrazoic Yellow 2G, 2G Pdr.	
Azoic Yellow Composition 2:	
Atlantic Printing Yellow 2G Pdr.	
Azogen Yellow GG Soln.	
Azogen Yellow GN	
Neutrazoic Yellow 2G, 2G Pdr.	
Azoic Yellow Composition 3:	
Neutrazoic Golden Yellow R, R Pdr.	
Azoic Orange Composition 3:	
Atlantic Printing Orange R, R Pdr., R Dbl, Soln.	
Direct Blue 14	72-57-1.
Carta Blue 3B	
Chrome Leather Blue 3B	
Diphenyl Blue 3B Conc.	
Direct Blue 3B Conc.	
Paper Blue 1	
Pergasol Blue 3B Conc.	
Direct Blue 25	2150-54-1.
Diazol Pure Blue BRA	
Diphenyl Brilliant Blue 5B	
Direct Brilliant Blue BC	
Direct New Blue 5B, 5B Conc.	
Fergasol Brilliant Blue 5B	
Pyazol New Blue	
Direct Blue 26	7082-31-7.
Direct Chrome Blue Black B Ex. Conc.	
Direct Orange 6	6637-88-3.
Amidine Orange GG	
Direct Fast Orange Y 125%	
Direct Red	992-59-6.
Amanil Purpurine 4B Conc.	
Benzopurpurine 4B Ex. Conc., 4B Special	
Cotton Red 4BS Supra	
Diphenyl Red 4BS Supra	
Direct Purpurine 4B	
Elcomine Benzopurpurine	
Paper Red 4BS Conc.	
Pergasol Red 4BS Conc.	
Direct Red 39	6358-29-8.
Amidine Scarlet 3B	
Atlantic Scarlet 3B	
Carta Red 3B	
Direct Fast Red 3B	
Elcomine Scarlet 3B	
Orcomine Scarlet 3B	
Pyrazol Red 3B	
Direct Brown 230:	
Direct Fast Brown BR-NB Conc.	
Direct Fast Brown BRLT	
Direct Yellow 95:	
Cuprophenyl Yellow 3GL	
Other Dyes derived from O-Tolidine:	
Diphenyl Green BBN	
Pyrazol Dark Green 3B	
Direct Fast Brown BCW-NB	
Direct Fast Brown BP-NB Conc.	
Direct Brown GG-NB	
Direct Brown US-NB	
Padazoic Yellow G Pdr.	
Padazoic Golden Yellow RLL Pdr.	
Padazoic Orange GR Pdr.	
Pentrating Black AM-NB	
Sandolan Red N-3B	
OTHER DYES CONTAINING BISAZOBIPHENYL MOIETY	
Acid Yellow 42	6375-55-9.
Calcocid Milling Yellow R	
Diamacide Yellow F-RA Conc.	
Xylene Milling Yellow SH	
Acid Red 97	10169-02-5.
Acid Anthracene Red G	
Acid Anthracene Red G Conc.	
Mordant Yellow 26	6232-49-1.
Berachrome Yellow RG	
Acid Red 89	6472-50-0.
Acid Anthracene Red 3B	
Acid Anthracene Red 3B Extra	
Amacid Milling Scarlet 3R Conc.	
Benzorco Milling Red 3BM	
Orcoacid Milling Red RN	
Orco Milling Red 3BM	
Acid Yellow 44	2429-76-7.
Amacid Milling Yellow 5G	
Acid Orange 63	15792-50-4.
Atlantic Fast Yellow PRA	
Sulfan Yellow PR	
Direct Blue 158	6655-95-4.
Cuprofix Blue C-FBL	
Intermet Brilliant Blue 2BL	
Direct Red 89:	
Intralite Scarlet BNLL	
Acid Red 99:	
Amacid Milling Red PRS	
Amacid Milling Red RST	
Milling Red RS 125%	
Orco Milling Red RS 125%	
Acid Red 111	6359-57-2.
Coomassie Scarlet B	
Levanol Fast Scarlet FGN	
Nylomine Scarlet C-3G	
Telon Fast Red GN	
M-Tolidine:	
Atanyl Scarlet FD	
O-Dianisidine/O-Tolidine:	
Direct Blue 3BX Conc.	
PIGMENTS DERIVED FROM DIANISIDINE	
Orange 16	6505-28-8.
Blue 25	10127-03-4
PIGMENTS DERIVED FROM DICHLOROBENZIDINE	
Orange 13	3520-72-7.
Orange 34	15793-73-4.
Yellow 12	6358-85-6.
Yellow 13	5102-83-0.
Yellow 14	5468-75-7.
Yellow 83	5567-15-7.
Chlorendic anhydride	115-27-5.
Chlorinated benzenes, mono- and di-.	108-90-7, 95-50-1, 541-73-1, 106-46-7.
Chlorinated benzenes, tri-, tetra-, penta- and Hexa-.	87-61-6, 120-82-1, 108-70-3, 634-66-2, 95-94-3, 608-93-5, 634-90-2.
Chlorinated naphthalenes—chlorinated derivatives of naphthalene (empirical formula $C_{10}H_xCl_y$ where $x+y=8$).	90-13-1, 1321-65-9, 1321-64-8, etc.
Chlorodifluoromethane	75-45-6.
Chlorophenols—meta-, ortho-, and para-chlorophenol.	108-43-0, 95-57-8, 106-48-9.
Chlorinated paraffins—chlorinated paraffin oils and chlorinated paraffin waxes, with chlorine content of 35 percent through 70 percent by weight.	
Chloromethane (methyl chloride)	74-87-3.
2-Chloro-1,3-butadiene (chloroprene).	126-99-8.
Cresols—ortho, meta, and para-cresol.	95-48-7, 108-39-4, 106-44-5.
Cyclohexanone	108-94-1.
1,2-Dichloroethane	75-34-3.
Dichloromethane. (methylene chloride).	75-09-2.
1,2-Dichloropropane	78-87-5.
Ethylbenzene	100-41-4.
Glycidol and its derivatives	556-52-5, 106-90-1, 106-91-2, 106-92-3, 2426-08-6, 2186-24-5, 122-60-1, 1675-54-3, etc.
Halogenated alkyl epoxides—halogenated noncyclic aliphatic hydrocarbons with one or more epoxy functional groups.	106-89-8, 3132-64-7, etc.
Hexachloro-1,3-butadiene	87-68-3.
Hexachlorocyclopentadiene	77-47-4.
Hydroquinone	123-31-9.
Iodomethane (methyl iodide)	74-88-4.
Isophorone	78-59-1.
Mesityl oxide	191-79-7.
4,4'-Methylenedianiline	101-77-9.
Methyl ethyl ketone	78-93-3.
Methyl isobutyl ketone	108-10-1.
Morpholine	110-91-8.
Nitrobenzene	98-95-3.
Nitrosodiethanolamine	102-71-6.
2-Nitropropane	79-46-9.
Organotin Compounds—compounds of tin containing at least one carbon-tin bond. Examples include, but are not limited to: mono-, di-, and trialkyl tin halides, carboxylates, ethers, etc.; mono-, di-, and triaryl tin halides, carboxylates, etc.; mixed alkyl aryl compounds; aralkyl derivatives; heterocyclic derivatives; tetraalkyl, tetraaryl and analogous terasubstituted tin derivatives.	54849-38-6, 25168-24-5, 77-58-7, 56-35-9, 16091-18-2, etc.
Pentachlorophenol	87-86-5.
p-Phenylenediamine	106-50-3.
Polychlorinated dibenzofurans.	
Polychlorinated dibenzo-p-dioxins.	
Polychlorinated terphenyls—polychlorinated ortho-, meta-, and para-terphenyls.	61788-33-8, 12642-23-8, 11126-42-4, etc.
Pyridine	110-86-1.

	CAS Numbers (examples for groups)
Quinone	106-51-4.
Toluene	108-88-3.
Toluene, alpha-chloro	100-44-7.
1,1,1,-Trichloroethane (methyl chloroform).	71-55-6.
2,4,5-Trichlorophenol	95-95-4.
Vinylbenzene (styrene)	100-42-5.
Vinyl fluoride	75-02-5.
Vinylidene fluoride	75-38-7.
Xylenes—ortho-, meta-, and para-xylene.	95-47-6, 108-38-3, 106-42-3.

716.44 [Reserved]

§ 716.15 Requirement to submit copies of studies.

(a)(1) Except as provided in section 716.18, any person who manufactures, processes, or distributes in commerce a chemical substance or mixture must send to EPA copies of any health and safety studies in his possession for each of the chemical substances or mixtures listed in section 716.13,

(i) That were conducted or initiated by or for him, or

(ii) That were conducted or initiated by a person who is not subject to reporting under this section.

(2) Underlying data, such as, medical or health records and daily monitoring records supporting exposure monitoring or epidemiological studies, do not have to be submitted unless requested (see paragraph (c) of this section).

(b) The studies must be accompanied by a cover letter containing the name, title, address, and telephone number of the submitting official, the name and address of the company on whose behalf the submission is made, and an index-list of submitted health and safety studies grouped by chemical substance or mixture and alphabetized by the last name of the senior author. The index-list must also contain the Chemical Abstracts Service (CAS) Registry Number, if known, of each chemical substance studied, including the CAS Registry Number of each intentional component of a mixture.

(c) Persons who submit studies may subsequently be required to submit all or part of any underlying data. In such cases, a letter will be sent to the person by certified mail from the designee of the Assistant Administrator for Toxic Substances, specifying the data to be submitted. Submissions must be postmarked within 30 days[1] of receipt of the letter, unless the letter specifies a longer period.

(d) Copies of health and safety studies and the accompanying index-lists and cover letter must be submitted (preferably by certified mail) to: Document Control Officer, Chemical Information Division, Office of Toxic Substances (TS-793), Environmental Protection Agency, Washington, DC 20460, Attention: 8(d) submission.

[1] The term "days" in this Part refers to calendar days unless otherwise stated.

§ 716.16 Requirement to submit lists of studies.

(a) All persons who presently manufacture, process, or distribute or propose to manufacture, process, or distribute one or more of the chemical substances or mixtures listed in section 716.13 of this Part, except as provided in section 716.18, must send the following to EPA for each of the chemical substances or mixtures listed in section 716.13 which they manufacture, process, or distribute or propose to manufacture, process, or distribute:

(1) A descriptive list of ongoing health and safety studies conducted by or for them, including the purpose of the study, type of data collected, and progress and anticipated date of completion. The list of health and safety studies shall include but not be limited to:

(i) Any health or medical records systems maintained by them on employees exposed or potentially exposed to a particular chemical(s).

(ii) Any studies or record systems, conducted or maintained by or for them, measuring or estimating concentrations of a particular chemical(s) anywhere in the environment, including the workplace.

(iii) Any studies or record systems, conducted or maintained by or for them, measuring or estimating human or environmental exposure to a particular chemical(s) anywhere in the environment, including the workplace;

(2) A copy of the protocol for each listed ongoing study.

(3) A list of health and safety studies, conducted by or for them, submitted to any Federal agency with no claims of confidentiality. The list should include the author, study title, name of the agency to which the study was sent, and any other identifying information with respect to the study.

(4) A list of any unpublished chemical and physical constants known to them.

(5) A list containing the study title and the identity and address of any person known to them to possess unpublished studies.

(b) Submissions under paragraph (a) of this section must be grouped by chemical, including CAS Number if known, and must be accompanied by a cover letter containing the name, job title, address and telephone number of the submitting official, and the name and address of the manufacturing, processing, or distributing establishment on whose behalf the submission is made.

(c) Persons who list studies may subsequently be required to submit all or part of any reports, including preliminary reports or underlying data. In such cases, a letter will be sent by certifying mail from the designee of the Assistant Administrator for Toxic Substances, specifying the data to be submitted. Submissions must be postmarked within 30 days of receipt of the letter, unless the letter specifies a longer period.

(d) The list of health and safety studies should be submitted (preferably by certified mail) to: Document Control Officer, Chemical Information Division, Office of Toxic Substances (TS-793), Environmental Protection Agency, Washington, DC 20460, Attention: 8(d) submission.

§ 716.17 Persons in possesssion of listed studies.

(a) Except as provided in section 716.18, any person who possesses a study that is listed by a person submitting a list according to the requirements of section 716.16 must, if requested by the designee of the Assistant Administrator for Toxic Substances, submit a copy of the study to EPA.

(b) In requiring any person to submit a copy of a study under paragraph (a) of this section, EPA shall notify the person in writing of the requirement.

(1) Such written notification shall include:

(i) A copy of this Part.

(ii) A description of the requested study.

(iii) The name, address, and telephone number of the person to whom the study is to be submitted.

(iv) The date by which the study must be submitted. However, such date shall be no sooner than 30 days after the person's receipt of the notification.

(2) The written notification shall be sent by certified mail.

§ 716.18 Information not subject to mandatory reporting.

Persons subject to this Part may, but are not required to, submit:

(a) Copies or lists of studies or data (such as physical/chemical constants) which have been published in the scientific literature; or

(b) Copies of any studies submitted to any Federal agency with no claims of confidentiality; or

(c) Copies of any studies conducted or initiated by or for another person who is subject to this Part; or

(d) Copies or lists of studies of mixtures containing a very small amount of one or more chemical substances listed in § 716.13, when the study clearly cannot reflect effects of the chemical substance(s).

§ 716.19 Schedule for submission of studies.

(a) Except as provided in paragraphs (b) and (c) of this section, submissions under §§ 716.15 and 716.16 shall be postmarked on or before 60 days after the effective date of the listing of a chemical in section 716.13.

(b) Persons subject to the requirements of section 716.16 must inform EPA of any study initiated within five years after the date the chemical substance or mixture was added to the list in section 716.13. Copies of final reports of studies listed as ongoing under section 716.16(a)(1), or studies initiated within the five-year reporting period, must be submitted within 30 days of the date they are obtained by persons required to report.

(c) Respondents who cannot meet the deadline for submissions required by this Part because of extraordinarily long file searches may apply for an extension of 20 days. Requests for extensions should be addressed to: Deputy Assistant Administrator for Program Integration and Information, Office of Toxic Substances (TS–793), Environmental Protection Agency, Washington, DC 20460.

§ 716.20 Sunset provision.

The reporting requirement on a chemical substance or mixture will terminate within 5 years after that chemical substance or mixture is added to the list in § 716.13. The termination date for the reporting requirement on a chemical substance or mixture will be the annual sunset date (May 1 or November 1) that falls within 5 years after reporting begins (e.g., a reporting requirement taking effect on January 1, 1980 would expire not later than November 1, 1984).

§ 716.21 Confidentiality claims.

(a) Any person submitting a document under this Part may assert a business confidentiality claim covering all or part of the submitted material. Any information covered by a claim will be disclosed by EPA only as provided in procedures set forth at 40 CFR Part 2, as amended on September 8, 1978, 43 FR 39997.

(b) If no claim accompanies a document at the time it is submitted to EPA, the document will be placed in an open file available to the public without further notice to the respondent.

(c)(1) Section 14(b) of TSCA states that EPA may not withhold from disclosure, on the grounds that they are confidential business information, health and safety studies of any substance that has been offered for commercial distribution or for which testing is required under TSCA section 4 or for which notice is required under TSCA section 5, except to the extent that disclosure of data from such studies would reveal:

(i) Processes used in the manufacturing or processing of a chemical substance or mixture, or

(ii) The portion of a mixture comprised by any of the chemical substances in the mixture.

(2) Any respondent who wishes to assert a claim that part of a study should be withheld from disclosure because disclosure would reveal a confidential process or quantitative mixture composition should explicitly explain the basis of the claim and clearly demarcate the material subject to the claim. Information in a study such as company name or address, financial statistics, or product codes used by a company, which is irrelevant to any health or environmental effect of a chemical, may be claimed confidential and not subject to the disclosure requirements of section 14(b) of TSCA.

(d) To assert a claim of confidentiality for data contained in a submitted document, the respondent must submit two copies of the document.

(1) One copy must be complete. In that copy the respondent must indicate what data, if any, are claimed as confidential by marking the specific information on each page with a label such as "confidential", "proprietary", or "trade secret".

(2) If some data are claimed as confidential, the respondent must submit a second copy. The second copy must be complete, except that all information claimed as confidential in the first copy must be deleted.

(3) The first copy will be for internal use by EPA. The second copy will be placed in an open file to be available to the public.

(4) Failure to furnish a second copy when information is claimed as confidential in the first copy will be considered a presumptive waiver of the claim of confidentiality. EPA will notify the respondent by certified mail that a finding of a presumptive waiver of the claim of confidentiality has been made. The respondent will be given 20 days from the date of receipt of notification to submit the required second copy. Failure to submit the second copy will cause EPA to place the first copy in the public file.

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